DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

5758

WARNING LETTER

March 2, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-51

Carolyn Raia, M.D.
Lead Interpreting Physician / Supervising Radiologist
Seaview Radiology, P. C.
256 Mason Avenue
Staten Island, New York 10305

Facility ID: #135632

Dear Dr. Raia:

Your facility was inspected on February 12th, 2001 by a representative of the New York City Department of Health, Bureau of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography operation at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography operations. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following repeat Level 2 noncompliance finding at your facility:

1. *The Radiologic Technologist, [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a repeat Level 2 noncompliance, because it identifies a failure to meet a significant MQSA requirement and indicates a failure by your facility to implement permanent correction of this problem.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

There were also four (4) non repeat Level 2 noncompliance findings that were listed on the inspection report provided at the close of the inspection. Those non-repeat Level 2 noncompliance findings were:

1. *The corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for the following:*

    a) *Unit #1, [redacted] in room #1.*
    b) *Unit #3, [redacted] in room #3.*
    c) *Unit #4, [redacted] in room #2.*

2. *The Interpreting Physician, [redacted], did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.*

In addition, there was also a repeat Level 3 noncompliance finding that was listed on the inspection report provided at the close of the inspection. The repeat Level 3 noncompliance finding was:

1. *The required personnel qualification documents were unavailable during the inspection.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- *The specific steps you have taken to correct the violation noted in this letter;*
- *Each step your facility is taking to prevent the recurrence of similar violations; and*
- *Sample records that demonstrate proper record keeping procedures.*

Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food and Drug Administration (FDA), P.O. Box 6057, Columbia, Maryland 21045-6057, Tel.: 1(800)/838-7715, or through the Internet at ***http://www.fda.gov***.

Sincerely yours,

Jerome G. Woyshner
District Director
New York District